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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,052	08/04/2005	Philippe Chenevier	1017753-000205	5521

21839 7590 10/08/2008  
BUCHANAN, INGERSOLL & ROONEY PC  
POST OFFICE BOX 1404  
ALEXANDRIA, VA 22313-1404

EXAMINER
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YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
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1618

NOTIFICATION DATE	DELIVERY MODE
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10/08/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/530,052	<b>Applicant(s)</b> CHENEVIER ET AL.	
	<b>Examiner</b> MICAH-PAUL YOUNG	<b>Art Unit</b> 1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/4/05</u> .  | 6) <input type="checkbox"/> Other: ____.                          |

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## **DETAILED ACTION**

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 8/4/05 was filed on the mailing date of the Specification on 8/4/05. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 and 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 contains the trademark/trade name Gelucire 50/13. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a mixture of saturated and polyunsaturated polyglycosylated glycerides and, accordingly, the identification/description is indefinite.

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Claim 12 recites that the coating composition comprises a surfactant, yet does not describe which of the two coating compositions recited in claim 1 would comprise the surfactant or lubricant. Claim 1 recites an enteric coating composition directly applied to the core and a further outer coating layer. For the purposes of examination the Examiner will interpret this claim to mean the enteric coating layer. Clarification is required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Chen et al (USPN 6,544,556 hereafter '556) in view of Saslawski et al (USPN 6,426,087 hereafter '087). The claims are drawn to a pharmaceutical formulation comprising a spheroid core with an enteric coating directly applied and an over coating applied to the enteric coating. The enteric coating comprises a mixture of enteric polymers and surfactants.

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The '556 patent teaches a pharmaceutical formulation comprising a spheroid core wherein the core comprises an active agent such as an NSAID and a proton pump inhibitor such as omeprazole (col. 5, lin. 35-col. 7, lin. 15). The spheroid core has an enteric coating directly applied to it (col. 4, lin. 4-15), where the coating comprises enteric polymers such as hydroxypropylcellulose phthalate, shellac and methacrylic acids along with plasticizers such as polyethylene glycol, along with surfactants like polysorbates (col. 10, lin. 10-25). The core comprises binders such as polyvinylpyrrolidone starches and sugars (col. 8, lin. 60-68). The core further comprises lubricants, and diluents (col. 9, lin. 15-30). The enteric coated spheroids are further coated with an outer coating comprises water soluble polymers such as sugars, polyvinylpyrrolidone and carboxymethylcellulose (col. 10, lin. 30-40). The spheroids are prepared by first making the core and then applying the successive coating compositions in a fluidized bed device (col. 14, lin. 9-16). Although the reference discloses an enteric coating formulation mixed with other coating polymers they are silent to the specific components of the instant claims. These components are well known in the art as shown in the '087 patent.

The '087 patent discloses a method of improving absorption of active agents by combine enteric coating materials with well known surfactants including mixtures of saturated and unsaturated polyglycosylated glycerides (abstract). The coating composition comprises a mixture of methacrylic enteric polymers and saturated and unsaturated polyglycosylated glycerides with melting points between 46-51 degrees Celsius and HLB values of 13 (examples 10, 12 and 15). It would have been obvious to include these polymers into the coating composition of the '556 in order to improve the absorption of the active agents.

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It would have been obvious to include the polymers of the '087 patent into the coating compositions of the '556 patent in order to improve the absorption of the active agents being coated. One of ordinary skill in the art would have been motivated to do so since both patents teach that these coating polymers can be applied directly to the drug containing core and discloses similar coating compositions. It would have been obvious to combine the teachings and suggestions as such with an expected result of stable core formulation useful in direct tableting with improved drug absorption properties.

### *Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 7:00-4:30; every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

/MICAHA-PAUL YOUNG/  
Examiner, Art Unit 1618